

REMARKS

The Applicants acknowledge the Examiner's Advisory Action with appreciation. Claims 9-16 remain pending in the application; however, method Claim 16 remains withdrawn as a result of the previously issued Restriction Requirement. The Office maintains a prior art rejection under 35 USC § 103.

Claims 9-15 remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of Lavielle, et al. (US Patent No. 5,472,979) in view of Helgason, et al. It remains the position of the Office that Lavielle, et al. disclose that the instant compound of formula (I) is capable of inhibiting platelet aggregation. The Office acknowledges that the Lavielle, et al. reference does not disclose combining the compound of formula (I) with aspirin and that the cited reference also does not disclose a compound of formula (I) having the (R) configuration; however, the Office reiterates its position that Helgason, et al. disclose a combination therapy consisting of aspirin and clopidogrel as a treatment regimen for the inhibition of platelet aggregation.

The Office maintains its position that, based on the disclosure of Helgason, et al., one skilled in the art would have been motivated to combine the platelet aggregation inhibitor of formula (I) with aspirin with a reasonable expectation of success that such a combination would be effective for the inhibition of platelet aggregation. With respect to the instantly claimed combinations comprising the (R) isomer of the compound of formula (I), it remains the position of the Office that one skilled in the art would recognize that the individual isomers of the compound of formula (I) would have different activity. The Office reiterates that one skilled in the art would have known how to resolve a racemic mixture of the compound of formula (I) and would have been motivated to do so with the expectation that the enantiomers would have substantially different pharmacological activity.

With respect to the Applicants' argumentation submitted with the Response and Amendment After Final of April 7, 2009 concerning the unexpected effects associated with the instantly claimed combinations, it remains the position of the Office that the Applicants' demonstration of synergistic effects is not commensurate

with the scope of the claims. In the Advisory Action, the Office states that the specification only demonstrates synergism for combinations comprising compound A at a dose from 0.01 mg/kg to 0.1 mg/kg and aspirin at a dose of 2 mg/kg.

The Applicants respectfully submit that one skilled in the art would recognize that the 2 mg/kg dose for aspirin used in the animal model study disclosed in the specification may be extrapolated to provide support for a dosage range in humans of 100 to 300 mg for aspirin, and that one skilled in the art would also recognize that the dosage range of 0.01 mg/kg to 0.1 mg/kg used in the disclosed animal model study may be extrapolated to provide support for a dosage range in humans of 1 to 300 mg for compound (A).

With the instant Amendment, the claims have been amended to recite combinations comprising compound A at a dosage range of 1 to 300 mg and aspirin at a dosage range of 100 to 300 mg. Thus, the Applicants respectfully submit that the synergistic effects associated with instantly claimed combinations, as amended, are supported by the animal model study disclosed in the specification.

Moreover, the Applicants respectfully reiterate that the synergistic effects associated with the instantly claimed combinations are not taught or suggested by the cited references of record in the application (alone or in combination). Thus, the Applicants respectfully submit that the instantly claimed combinations are not rendered obvious by the cited references. Reconsideration and withdrawal of the obviousness rejection under 35 USC § 103(a) is respectfully requested.

Finally, and in accordance with MPEP § 821.04, the Applicants request that the Office rejoin non-elected method Claim 16 upon the identification of allowable subject matter.

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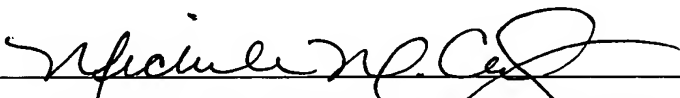
Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, rejoinder of the non-elected method claim, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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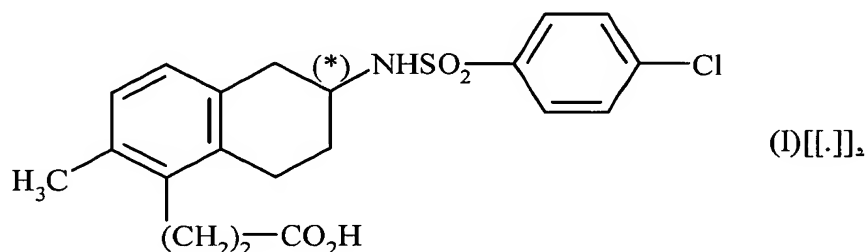
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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.

LISTING OF CLAIMS

Claims 1-8 (CANCELED)

9- (currently amended) A composition comprising a combination of compound (A) of formula (I), optionally in the form of an optical isomer, or a pharmaceutically acceptable salt thereof, and aspirin, or a pharmaceutically acceptable salt thereof:



wherein compound (A) of formula (I), or an optical isomer or pharmaceutically acceptable salt thereof, is present in a range of from 1 to 300 mg, and aspirin, or a pharmaceutically acceptable salt thereof is present in a range of from 100 to 300 mg.

10- (previously presented) The composition of claim 9, wherein compound (A) has the (R) configuration.

11- (previously presented) The composition of claim 9, wherein compound (A) is in the form of a sodium salt.

12- (currently amended) A pharmaceutical composition comprising as active ingredients a combination of compound (A), optionally in the form of an optical isomer, or a pharmaceutically acceptable salt thereof, and aspirin, or a pharmaceutically acceptable salt thereof, wherein compound (A), or an optical isomer or pharmaceutically acceptable salt thereof, is present in a range of from 1 to 300 mg, and aspirin, or a pharmaceutically acceptable salt thereof is present in a range of from 100 to 300 mg, in combination with one or more pharmaceutically acceptable, inert excipients or carriers.

13- (previously presented) The pharmaceutical composition of claim 12, wherein compound (A) has the (R) configuration.

14- (previously presented) The pharmaceutical composition of claim 12, wherein compound (A) is in the form of a sodium salt.

5 15- (canceled)

16- (withdrawn) A method for treating a living animal body, including a human, afflicted with an atherothrombotic illness involving activation of TP receptors and/or formation of metabolites, comprising the step of administering to the living animal body, including a human, an amount of a composition of claim 9 which is effective for alleviation of the
10 atherothrombotic illness.